

Application Number 10/773,121  
Amendment dated December 7, 2005  
Responsive to Office Action mailed September 7, 2005

### AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

#### **Listing of Claims:**

**Claim 1 (Original):** A stimulation lead introducer comprising:

an elongated dilator defining a dilator lumen sized to advance over a guidewire, the dilator having a substantially conical distal tip, wherein at least a portion of the conical distal tip has a substantially oblong cross-section; and

an elongated sheath defining a sheath lumen sized to accommodate the dilator or the stimulation lead.

**Claim 2 (Original):** The stimulation lead introducer of claim 1, wherein the sheath has a substantially oblong cross-section.

**Claim 3 (Original):** The stimulation lead introducer of claim 1, wherein the sheath has a substantially oblong cross-section with a width of the cross-section of the sheath that is greater than approximately two times a height of the cross-section of the sheath.

**Claim 4 (Original):** The stimulation lead introducer of claim 1, wherein the dilator lumen has a substantially oblong cross-section.

**Claim 5 (Original):** The stimulation lead introducer of claim 1, wherein the sheath lumen has a substantially oblong cross-section.

**Claim 6 (Original):** The stimulation lead introducer of claim 1, wherein the sheath comprises a material that is substantially deformable.

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**Claim 7 (Original):** The stimulation lead introducer of claim 6, wherein the material is polyethylene.

**Claim 8 (Original):** The stimulation lead introducer of claim 1, wherein the dilator comprises a material that is substantially deformable.

**Claim 9 (Original):** The stimulation lead introducer of claim 8, wherein the material is polyethylene.

**Claim 10 (Original):** The stimulation lead introducer of claim 1, wherein the dilator is at least as long as the sheath.

**Claim 11 (Original):** The stimulation lead introducer of claim 1, wherein the substantially conical distal tip comprises a proximal opening and a distal opening, the proximal opening having a substantially oblong cross-section and the distal opening having a substantially circular cross-section.

**Claim 12 (Original):** The stimulation lead introducer of claim 1, wherein the substantially conical distal tip comprises a proximal opening having an oblong cross-section such that a width of the proximal opening is greater than a height of the proximal opening.

**Claim 13 (Original):** The stimulation lead introducer of claim 12, wherein the width of the proximal opening is greater than or equal to approximately three times the height of the proximal opening.

**Claim 14 (Original):** The stimulation lead introducer of claim 1, wherein the sheath includes radiopaque material that is viewable under fluoroscopic imaging.

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Claim 15 (Original): The stimulation lead introducer of claim 1, wherein the sheath lumen has a cross-section with a width of the cross-section of the sheath lumen that is greater than approximately two times a height of the cross-section of the sheath lumen.

Claim 16 (Original): A method for introducing a stimulation lead comprising:  
inserting a stimulation lead introducer into an epidural region proximate a spine of a patient via a guidewire, wherein the introducer includes:

an elongated dilator defining a dilator lumen sized to advance over the guidewire, the dilator having a substantially conical distal tip, wherein at least a portion of the conical distal tip has a substantially oblong cross-section, and

an elongated sheath defining a sheath lumen sized to accommodate the dilator or the stimulation lead;

withdrawing the dilator from the sheath; and

introducing a stimulation lead to a target site within the epidural region via the sheath.

Claim 17 (Original): The method of claim 16, further comprising:

inserting a needle with a stylet into the epidural region proximate a spine of a patient;

withdrawing the stylet from the needle;

inserting the guidewire into the needle such that a distal end of the guidewire extends to the target site within the epidural region;

withdrawing the needle;

inserting the stimulation lead introducer into the patient via the guidewire following withdrawal of the needle;

withdrawing the guidewire; and

introducing the stimulation lead via the sheath following withdrawal of the dilator and the guidewire.

Claim 18 (Original): The method of claim 17, further comprising withdrawing the sheath.

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Claim 19 (Original): The method of claim 17, further comprising activating the stimulation lead to stimulate a nerve.

Claim 20 (Original): The method of claim 17, further comprising attaching a syringe to the needle, prior to inserting the guidewire into the needle, and attempting to inject fluid into the epidural region via the syringe and the needle to evaluate a position of the needle.

Claim 21 (Original): The method of claim 17, further comprising using an imaging technique to visualize introduction of the stimulation lead.

Claim 22 (Original): The method of claim 21, wherein the imaging technique comprises fluoroscopic imaging.

Claim 23 (Original): The method of claim 17, wherein the needle is a Tuohy needle.

Claim 24 (Original): The method of claim 16, wherein the sheath has a substantially oblong cross-section.

Claim 25 (Original): The method of claim 16, wherein the sheath has a substantially oblong cross-section with a width of the cross-section of the sheath that is greater than approximately two times a height of the cross-section of the sheath.

Claim 26 (Original): The method of claim 16, wherein the dilator lumen has a substantially oblong cross-section.

Claim 27 (Original): The method of claim 16, wherein the sheath lumen has a substantially oblong cross-section.

Claim 28 (Original): The method of claim 16, wherein the sheath comprises a material that is substantially deformable.

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Claim 29 (Original): The method of claim 28, wherein the material is polyethylene.

Claim 30 (Original): The method of claim 16, wherein the dilator comprises a material that is substantially deformable.

Claim 31 (Original): The method of claim 30, wherein the material is polyethylene.

Claim 32 (Original): The method of claim 16, wherein the dilator is at least as long as the sheath.

Claim 33 (Original): The method of claim 16, wherein the substantially conical distal tip comprises a proximal opening and a distal opening, the proximal opening having a substantially oblong cross-section and the distal opening having a substantially circular cross-section.

Claim 34 (Original): The method of claim 16, wherein the substantially conical distal tip comprises a proximal opening having an oblong cross-section such that a width of the proximal opening is greater than a height of the proximal opening.

Claim 35 (Original): The method of claim 34, wherein the width of the proximal opening is greater than or equal to approximately three times the height of the proximal opening.

Claim 36 (Original): The method of claim 16, wherein the sheath includes radiopaque material that is viewable under fluoroscopic imaging.

Claim 37 (Original): The method of claim 16, wherein the sheath lumen has a cross-section with a width of the cross-section of the sheath lumen that is greater than approximately two times a height of the cross-section of the sheath lumen.

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**Claim 38 (Original):** A dilator for widening a path for a stimulation lead to travel through an epidural region proximate a spine of a patient, the dilator having a proximal end and a distal end, wherein the dilator defines a dilator lumen sized to advance over a guidewire, the dilator having a substantially conical distal tip, wherein at least a portion of the conical distal tip has a substantially oblong cross-section.

**Claim 39 (Original):** The dilator of claim 38, wherein the dilator is formed from a material that is substantially deformable.

**Claim 40 (Original):** The dilator of claim 39, wherein the material is polyethylene.

**Claim 41 (Original):** The dilator of claim 38, wherein the dilator lumen has a substantially oblong cross-section.

**Claim 42 (Original):** The dilator of claim 38, wherein the substantially conical distal tip comprises a proximal opening and a distal opening, the proximal opening having a substantially oblong cross-section and the distal opening having a substantially circular cross-section.

**Claim 43 (Original):** The dilator of claim 42, wherein the width of the proximal opening is greater than or equal to approximately three times the height of the proximal opening.

**Claim 44 (New):** The stimulation lead introducer of claim 1, wherein a width of an outside of the sheath is within a range from approximately 5.21 millimeters to approximately 7.75 millimeters, and a height of the outside of the sheath is within a range from approximately 3.05 millimeters to approximately 3.56 millimeters.

**Claim 45 (New):** The stimulation lead introducer of claim 1, wherein the dilator and the sheath are sized for insertion into an epidural region of a patient.

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Claim 46 (New): A kit comprising:

a stimulation lead introducer, wherein the stimulation lead introducer includes:

an elongated dilator defining a dilator lumen sized to advance over a guidewire, the dilator having a substantially conical distal tip, wherein at least a portion of the conical distal tip has a substantially oblong cross-section, and

an elongated sheath defining a sheath lumen sized to accommodate the dilator or the stimulation lead; and

the stimulation lead, wherein a distal end of the stimulation lead has a substantially oblong cross-section and includes at least one electrode.

Claim 47 (New): The kit of claim 46, wherein the distal end of the stimulation lead has a substantially rectangular cross-section.

Claim 48 (New): The kit of claim 46, wherein the distal end of the stimulation lead is substantially paddle-shaped.

Claim 49 (New): The kit of claim 46, wherein a width of an outside of the sheath is within a range from approximately 5.21 millimeters to approximately 7.75 millimeters, and a height of the outside of the sheath is within a range from approximately 3.05 millimeters to approximately 3.56 millimeters, and the distal end of the stimulation lead has a width within a range from approximately 3.81 millimeters to approximately 4.32 millimeters and a height within a range from approximately 1.02 millimeters to approximately 1.40 millimeters.

Claim 50 (New): The kit of claim 46, wherein the dilator and the sheath are sized to enter an epidural region of a patient.